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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Grüber, et al.

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Docket: 855-15

For: PANCREATIC LIPASES AND/OR
RECOMBINANT COLIPASES AND
DERIVED POLYPEPTIDES PRODUCED
BY PLANTS, METHODS FOR
OBTAINING THEM AND USE
THEREOF

Dated: April 19, 1999

Assistant Commissioner for Patents
Washington, DC 20231

PRE AMEND/A
AJ
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8-23-99

PRELIMINARY AMENDMENT

Sir:

The following Amendment is submitted prior to examination to place the claims in condition to conform to United States practice. Entry of this amendment and examination on the merits are respectfully requested.

IN THE SPECIFICATIONS:

- ✓ On page 5, line 30, delete "derived".
- ✓ On page 5, line 31, after "polypeptide" insert "derived therefrom".
- ✓ On page 6, line 13, delete "derived polypeptide" and insert "polypeptide derived therefrom".
- ✓ On page 6, line 13, delete "elements" and insert "nucleic acid sequences".

✓ On page 6, line 14, delete "derived polypeptide" and insert "polypeptide derived therefrom".

✓ On page 6, line 22, delete "derived polypeptide" and insert "polypeptide derived therefrom".

✓ On page 6, line 32, delete "elements" and insert "nucleic acid sequences".

On page 6, line 33, delete "derived polypeptide" and insert "polypeptide derived therefrom".

On page 6, line 37, delete "derived polypeptide" and insert "polypeptide derived therefrom".

✓ On page 7, line 30, delete "elements" and insert "nucleic acid sequences".

✓ On page 7, line 31, delete "derived polypeptide" and insert "polypeptide derived therefrom".

A1 On page 9, line 23, after "peptide", insert "(for example, a signal peptide)".

A2 On page 9, line 26, after "peptide", insert "(for example, a signal peptide)".

A3 On page 10, line 28, after "peptide", insert "(for example, a signal peptide)".

A4 On page 11, line 4, after "peptide", insert "(for example, a signal peptide)".

A5 On page 11, line 8, after "peptide", insert "(for example, a signal peptide)".

A6 On page 11, line 14, after "peptide", insert "(for example, a signal peptide)".

A7 On page 11, line 15, after "peptide", insert "(for example, a signal peptide)".

A8 On page 11, line 17, after "peptide", insert "(for example, a signal peptide)".

✓ On page 14, line 30 delete "derived polypeptide" and insert "polypeptide derived therefrom".

✓ On page 16, line 23 delete "derived polypeptides" and insert "polypeptides derived therefrom".

✓ On page 16, line 28 delete "derived polypeptide(s)" and insert "polypeptide(s) derived therefrom".

✓ On page 16, line 35 delete "derived polypeptide(s)" and insert "polypeptide(s) derived therefrom".

IN THE CLAIMS:

Please amend Claims 1-26 as follows:

~~1. (Amended) A method of use [Use] of a recombinant nucleotide sequence [containing] comprising [firstly] a cDNA coding for an element of [the] pancreatic lipase-colipase complex of mammals or for a protein derived therefrom or a [derived] polypeptide derived therefrom, and [secondly the] nucleic acid sequences [elements enabling] which enable a plant cell to produce this element of the pancreatic lipase-colipase complex, or the protein or the [derived] polypeptide derived therefrom, coded by said cDNA, in particular a promoter and a transcription terminator recognised by [the] transcriptional machinery of the plant cells, for transforming plant cells, [with a view] to [obtaining] obtain, from these cells, or from plants obtained from the latter, a recombinant element of the pancreatic lipase-colipase complex of mammals, or a protein derived therefrom or [derived] polypeptide derived therefrom.~~

--2. (Amended) A method of use [Use] in accordance with claim 1[, characterised in that] wherein the element of the pancreatic lipase-colipase complex is pancreatic lipase.

--3. (Amended) A method of use [Use] in accordance with claim 1[, characterised in that] wherein the element of the pancreatic lipase-colipase complex is colipase.

--4. (Amended) A method of use [Use] of the sequences in accordance with [claims 2 and] claim 3 for [the] co-transformation of plant cells [with a view to obtaining] to obtain, from these cells, or from plants obtained from the latter, a recombinant mammalian pancreatic lipase and colipase, or their derivatives.

--5. (Amended) A recombinant [Recombinant] nucleotide sequence[, characterised in that it contains] comprising [firstly the] a sequence coding for an element of [the] pancreatic lipase-colipase complex or a protein derived therefrom or a [derived] polypeptide derived therefrom, and [secondly the elements enabling] nucleic acid sequences which enable a plant cell to produce an element of the pancreatic lipase-colipase complex or a protein derived therefrom or [derived] polypeptide derived therefrom coded by said sequence, in particular a promoter and a transcription terminator recognised by [the] transcriptional machinery of the plant cells.

--6. (Amended) A recombinant [Recombinant] nucleotide sequence in accordance with claim 5[, characterised in that] wherein the element of the pancreatic lipase-colipase complex is pancreatic lipase.

--7. (Amended) A recombinant [Recombinant] nucleotide sequence in accordance with claim 5[, characterised in that] wherein the element of the pancreatic lipase-colipase complex is colipase.

--8. (Amended) A recombinant [Recombinant] nucleotide sequence[, characterised in that it contains] comprising [firstly the] sequences coding for a pancreatic lipase and a colipase or [the] proteins or [derived] polypeptides derived therefrom, and [secondly the elements enabling] nucleic acid sequences which enable a plant cell to produce a pancreatic lipase and a colipase or [the] proteins derived therefrom or [derived] polypeptides derived therefrom coded by said sequence, in particular a promoter and a transcription terminator recognised by [the] transcriptional machinery of the plant cells.

--9. (Amended) A vector [Vector], in particular a plasmid vector, [containing] comprising a nucleotide sequence in accordance with [any of claims 5 to] claim 5 or claim 6 or claim 7 or claim 8, inserted at a site that is non-essential for its replication.

--10. (Amended) A host [Host] cell, in particular any bacterium such as *Agrobacterium tumefaciens*, transformed by a vector in accordance with claim 9.

--11. (Amended) A method [Method] for obtaining an element of [the] recombinant pancreatic lipase-colipase complex, or a protein or [derived] polypeptide derived therefrom, [characterised in that] wherein the method [it] comprises :

- the transformation of plant cells, in particular using a host cell according to claim 10, itself transformed by a vector according to claim 9, such as to incorporate in [the] genome of these cells a recombinant sequence in accordance with claim 5

- optionally, obtaining transformed plants from the [above-mentioned] transformed cells,

- recovery of the element of the recombinant pancreatic lipase-colipase complex or the protein or [derived] polypeptide derived therefrom produced in said [above-mentioned] cells or transformed plants, in particular by extraction, optionally followed by purification.

--12. (Amended) The production [Production] method, in accordance with claim 11, [characterised in that] wherein the element of the pancreatic lipase-colipase complex is pancreatic lipase.

--13. (Amended) The production [Production] method, in accordance with claim 12[, characterised in that] wherein the element of the pancreatic lipase-colipase complex is colipase.

--14. (Amended) The co-production [Co-production] method of recombinant pancreatic lipase and colipase, or the protein or [derived] polypeptide derived therefrom, [characterised in that it] wherein the method comprises :

- the transformation of plant cells, in particular using a host cell in accordance with claim 10, itself transformed by a vector in accordance with claim 9, such as to

incorporate into the genome of these cells a recombinant sequence in accordance with claim

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- optionally obtaining transformed plants from the above-mentioned transformed cells,
- recovery of the recombinant pancreatic lipase and colipase or proteins derived therefrom or [derives] polypeptides derived therefrom produced in said [above-mentioned] cells or transformed plants, in particular by extraction, followed if necessary by purification.

--15. (Amended) Plants, or parts of plants, in particular leaves and/or fruits and/or seeds and/or plant cells, genetically transformed[, characterised in that] wherein they contain one (or more) recombinant nucleotide sequence(s) in accordance with [any of claims 5 to] claim 5 or claim 6 or claim 7 or claim 8, incorporated in stable manner in their genome, these plants [being chosen in particular] selected from the group consisting of colza, tobacco, maize, pea, tomato, carrot, wheat, barley, potato, soybean, sunflower, lettuce, rice, alfalfa and beetroot.

--16. (Amended) A recombinant [Recombinant] pancreatic lipase or protein or [derived] polypeptide derived therefrom [characterised in that] wherein it is obtained using the method of claim 12 or 14.

--17. (Amended) A recombinant [Recombinant] colipase or protein or derived polypeptide, [characterised in that] wherein it is obtained using the method of claim 13 or 14.

--18. (Amended) An association [Association] of recombinant pancreatic lipase and colipase or protein derived therefrom or [derived] polypeptide derived therefrom [, characterised in that] wherein it is obtained using the method of claim 14.

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--19. (Amended) A plant [Plant] extract having enzymatic activity such as obtained by implementing a method [of any of claims 11 to] according to claim 11 or claim 12 or claim 13 or claim 14 [, characterised in that] wherein it [contains] comprises recombinant pancreatic lipase and/or recombinant colipase or the proteins or [derived] polypeptides derived therefrom.

--20. (Amended) A method of use [Use] of plants, or parts of plants, in accordance with claim 15, and/or plant extracts in accordance with claim 19, and/or proteins or polypeptides or an association thereof in accordance with claims 16 to 18, to obtain medicinal products intended for the treatment of pathologies associated with deficient lipase production in [the] a body, such as cystic fibrosis or for [the] treatment of eating disorders, such as obesity.

--21. (Amended) A pharmaceutical [Pharmaceutical] product[, characterised in that it comprises] comprising plants, or parts of plants in accordance with claim 15, and/or plant extracts in accordance with claim 19, and/or proteins or polypeptides or an association thereof in accordance with claims 16 to 18, possibly in association with one or more pharmaceutically acceptable vehicles or excipients.

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--22. (Amended) A method of use [Use] of plants, or parts of plants, in accordance with claim 15, and/or plant extracts in accordance with claim 19, and/or proteins or polypeptides or an association therefore in accordance with [claims 16 to] claim 16 or claim 17 or claim 18, to obtain foods intended for human or animal use, in particular functional foods more particularly intended to facilitate [the] absorption of animal or vegetable fats ingested by healthy persons or those suffering from one or more pathologies which may or may not affect [the] production level of gastric and/or pancreatic lipase.

--23. (Amended) Functional foods [characterised in that they] which comprise plants, or parts of plants in accordance with claim 15, and/or plant extracts in accordance with claim 19, and/or proteins or polypeptides or an association thereof in accordance with [claims 16 to] claim 16 or claim 17 or claim 18, possibly in association with at least one [(or more)] other edible [compound(s)] compounds.

--24. (Amended) The method of use [Use] of plants, or parts of plants in accordance with claim 15, and/or plant extracts in accordance with claim 19, and/or proteins or polypeptides or an association thereof in accordance with [claims 16 to] claim 16 or claim 17 or claim 18, to implement enzymatic reactions in industrial, agro-food and agro-industrial areas, in particular [the] fat and lipochemistry industries and [the] dairy industry.

--25. (Amended) Enzymatic preparations intended for industrial, agro-food or agro-industrial applications, able to be used in accordance with claim 24, and comprising plants or parts of plants in accordance with claim 15, and/or plant extracts in accordance with claim 19,

and/or proteins or polypeptides or an association thereof in accordance with [claims 16 to] claim 16 or claim 17 or claim 18.

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--26. (Amended) The method of use [Use] of plants, or parts of plants, in accordance with claim 15, and/or plant extracts in accordance with claim 19, and/or proteins or polypeptides or an association thereof in accordance with [claims 16 to] claim 16 or claim 17 or claim 18, to obtain biofuels.

REMARKS

The present application was originally filed as an international application. This Preliminary Amendment is being filed in order to place the application in a form which is in compliance with United States Patent practice.

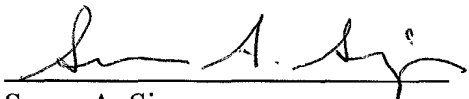
As originally filed, Claims 1-4, 20, 22, 24 and 26 were written as "use" claims. These claims have been rewritten as "method" claims. Additionally, the multiple dependencies in the claim 4 have been removed.

Inasmuch as the present amendment does not introduce new subject matter and, in any event, places the application in better condition for consideration on the merits, entry hereof is respectfully requested.

Applicants believe that no fees are due with the amendment of the claims. However, the PTO is authorized to charge Deposit Account No. 08-2461 if it is determined that any fees are due.

A duplicate copy of this sheet is enclosed for that purpose.

Respectfully submitted,



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